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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,558	08/27/2001	Lixiao Wang	S63.2-9482	4996

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EXAMINER
BRUENJES, CHRISTOPHER P

ART UNIT	PAPER NUMBER
1772	5

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,558	WANG, LIXIAO	
	Examiner	Art Unit	
	Christopher P Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *14-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a medical tube, classified in class 428, subclass 36.9.

II. Claims 17-58, drawn to different methods for making medical components, classified in classes 29, 264, and 427.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another materially different process such as one, which does not require inserting an inner shaft into an outer shaft.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Species IA, drawn to a medical tube, and corresponding to claims 1-13; Species IB, drawn to a medical device, and corresponding to claims 14-16; Species IIA, drawn to a method of making a catheter, and corresponding to claims 17-24; Species IIB, drawn to a method of making a catheter balloon, and corresponding to claims 25-29; Species IIC, drawn to a method of making a medical device chosen from a particular group, and corresponding to claims 30-36; Species IID, drawn to a method of making a stent delivery catheter, and corresponding to claims 37-49; Species IIE, drawn to a method of making a medical multi-layered tube, and corresponding to claims 50-58.

4. Applicant must first elect between product and process claims. If Applicant elects either the product or process claims, then only one species group within respective product or process claims my be selected for examination.

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. During a telephone conversation with Bill Anderson on February 12, 2003 a provisional election was made without traverse to prosecute the invention of Group I, Species IA, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

10. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such

as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

11. The abstract of the disclosure is objected to because the word "comprising" is legal phraseology and is not allowed in an abstract. "Comprising" should be replaced with "contains" or "includes". Also for clarification in the abstract "PTFE" must be written out so that it is completely understood what "PTFE" refers to without reading the specification. The heading "Stent Delivery System" is not allowed because the only heading for the abstract is "Abstract of the Disclosure". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 6-7, and 9-10, the limitation "melt-processible PTFE" renders the claims vague and indefinite because "melt-processible" it is not understood what makes a polytetrafluoroethylene "melt-processible" and what makes it different composition or structurally from other polytetrafluoroethylene. Also "PTFE" must be written out, in order to clarify what "PTFE" refers to.

Claims 2-5, 8, and 11-13 are rejected based on their dependency on rejected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United

States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-4 and 6-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Garabedian et al (USPN 6,508,805).

Garabedian et al teach a medical tube comprising at least a first layer and a second layer, wherein the second layer is extruded polytetrafluoroethylene (col.4, l.11-14), which is melt-processible polytetrafluoroethylene because it is extruded. The medical tube is a catheter, section of a catheter or catheter balloon (see abstract). The first layer is a thermoplastic polymer such as polyether block amide, which is a polyamide (col.5, l.59-60). The tube further comprises a third layer of polytetrafluoroethylene so that the polyamide is sandwiched between the two layers of polytetrafluoroethylene (col.7, l.25-26). The polytetrafluoroethylene is in contact with the outer side of the first layer (col.7, l.25-26). The tie layer between the second and first layer bonds the first and second layer to each other through the braided reinforcement layer, therefore through adhesive bonding the polytetrafluoroethylene of the second layer contacts the inner side of the first layer (col.4, l.15-25). The method of forming the medical tube by extrusion or coextrusion receives little patentable weight within article claims, because materially

different processes can make the same structure. Also, the intended use of the medical tube receives little patentable weight because the same structure can be used for many different purposes. Therefore, only structure is used to define an article, in which "catheter tube", "inner and outer catheter shaft", and "catheter balloon" do not define any structure and therefore receive little patentable weight.

14. Claims 1-6 and 9-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Saitou et al (USPN 6,451,005).

Saitou et al anticipate a medical tube comprising a tube that is a catheter, catheter shaft, or catheter balloon (see abstract), comprising a first layer and second layer, wherein the second layer is polytetrafluoroethylene (col.9, l.56-62). The first layer comprises a fluorocarbon resin including either polytetrafluoroethylene or a perfluoroalcoxy resin (or perfluoroalkyl resin), which includes perfluoroalcoxy vinyl ether with polytetrafluoroethylene, known as PFA, which is a perfluoroalcoxy resin (col.13, l.48-58). The first and second layers are extruded, therefore the layers melt-processible (col.14, l.32-37 and col.15, l.18-21). The first and second layers are either polytetrafluoroethylene or one of the other thermoplastic resins such as perfluoroalcoxy resin or polyamide.

The outer layer flows into the gap between the adjacent windings of the coil and adhere to the periphery of the inner layer. In this way the inner and outer layer contact each other (col.15, l.7-11). Therefore because the inner or outer layer is the first or second layer reversibly, then the polytetrafluoroethylene contacts the inner side of the first layer in one embodiment and the outer side of the first layer in another embodiment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitou et al (USPN 6,451,005) in view of Garabedian et al (USPN 6,508,805).

Saitou et al teach all that is claimed in claim 1, but fails to explicitly teach a third layer. However, Garabedian et al teach that polytetrafluoroethylene is required on both the innermost and outermost layer of a medical tube, because of its biocompatibility and lubricious behavior (col.4, l.4-14 and col.7, l.25-26). Saitou et al teach that the inner layer is preferably polytetrafluoroethylene, but teaches that the other layer is any flexible polymer. One of ordinary skill in the art would have recognized that a third layer is added to a medical tube to ensure that a polytetrafluoroethylene layer is present on both the innermost and outermost layers, because of its ability in biocompatibility and lubricious behavior.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to extrude a third layer composed of polytetrafluoroethylene to the outside of the outer layer of

Saitou et al in order to improve the biocompatibility and lubricious behavior of the outside of the medical tube, which is important when using the medical tube as a catheter inserted into a human body, as taught by Garabedian et al.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tomaschko et al (US 2003/0023261); Brauker et al (USPN 6,517,571); Garabedian et al (USPN 6,71,295).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 703-305-3440. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 703-308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

March 6, 2003

HAROLD PYON
SUPERVISORY PATENT EXAMINER

3/6/03